R E M A R K S

Reconsideration of the application is respectfully requested based on the following remarks.

Claims 105-121 are pending. In the Office Action, the Examiner rejected claims 105-117 and claims 118-121 were withdrawn from consideration. Claims 105-112, 117 and 118 have been amended herein.

RESTRICTION REQUIREMENT UNDER 35 USC §121

In the Office Action, the Examiner has required restriction between subcombinations usable together. Applicant is required to elect a single subcombination from among groups:

I. Claims 105-117, drawn to an optical fiber or micro tube terminating with a circular reagent pad, classified in class 422, subclass 82.05; and

II. Claims 118-121, drawn to a ball point shaped device for testing glucose, classified in class 422, subclass 61.

Applicant provisionally elects group I, comprising claims 105-117, with traverse.

The Examiner stated that, "Inventions I and II are related as subcombinations disclosed as usable together in a single combination." Applicant respectfully disagrees. Independent claim 118, of group II, is a combination claim where the combination as claimed requires the details of subcombination claim 112, of group I, as separately claimed. As such there is no evidence that combination claim 118 is patentable without the details of subcombination claim 112. The inventions are not distinct and a requirement for restriction cannot be made or maintained, even if the subcombination has separate utility. See MPEP § 806.05(c).

The restriction requirement is further traversed on the grounds that it should not be a serious burden on the Examiner to search database literature generally in connection

with the examination of group I for a test tip device for a photometrical detector used for measuring a quantity of an analyte and claims of group II for an apparatus for a blood glucose self-monitoring system. The Examiner shows that group I is classified in class 422, subclass 82.05 (class: CHEMICAL APPARATUS AND PROCESS DISINFECTING, DEODORIZING, PRESERVING, OR STERILIZING, subclass: Measuring optical property by using ultraviolet, infrared, or visible light). The Examiner shows that group II is classified in class 422, subclass 61 (class: CHEMICAL APPARATUS AND PROCESS DISINFECTING, DEODORIZING, PRESERVING, OR STERILIZING, subclass: Test package or kit). The art of record cited by the Examiner in rejection of claims in group I, include classifications in classes 350, 356, 385 and 422. These references provide various teachings regarding blood glucose testing. Applicant's group II claims are directed to an apparatus for a blood glucose self-monitoring system. As discussed above, Applicant believes that independent claim 118, of group II, is a combination claim where the combination as claimed requires the details of subcombination claim 112. Since the Examiner has conducted a proper search regarding the details of claim 112, Applicant does not believe that the additional details of group II imposes a serious burden, if any, on the Examiner to search database literature.

Applicant respectfully requests the Examiner to withdraw the restriction requirement and rejoin claims 118-121.

CLAIM REJECTIONS UNDER 35 USC §112

In the Office Action, the Examiner rejected claims 105-117 under 35 U.S.C. 112, second paragraph, as being indefinite. The Examiner stated that claims 105 and 112 are not clear if the first, second or both ends have the first diameter. Applicant has herein amended claims 105 and 112 to clarify that both ends have the same diameter.

The Examiner stated that claims 106-111 contain a reoccurring typographical error. Applicant has herein amended claims 106-111 to correct this error.

The Examiner stated that in claim 107 it is not clear what structural limitations the first and second ends being polished intend. Applicant has herein amended claim 107 to include a limitation.

Applicant believes that the above issues have been fully addressed and respectfully request the Examiner to withdraw the 35 U.S.C. 112 rejections.

REJECTION OF CLAIMS 105-108, 110-114 and 116-117 UNDER 35 USC §102(e)

In the Office Action, the Examiner rejected claims 105-108, 110-114 and 116-117 under 35 U.S.C. 102(e) as being clearly anticipated by Raskas (USP 6,157,442). The Examiner stated, "The Office has read the claimed "optical fiber" on the taught "optical fiber", the claimed "first end" on the taught "first end", the claimed "second end" on the taught "second end" and the claimed "reagent pad" on the taught "tip portion." Applicant respectfully disagrees.

Raskas shows and describes a sensor device for measuring a concentration of a substance within a sample. A sensor comprising an optical fiber portion having a first end and a second end, the second end having a tip portion attached thereto and an active material incorporated within the tip portion. The tip portion adapted to be inserted into a sample. The active material is capable of interacting with a substance within a sample. A light source is coupled to the first end of the sensor for emitting a beam of light into and through the sensor and into a sample (Abstract). The tip device 38 includes a non-tapered fiber optic portion 60 and a tapered fiber optic portion 62, which is coated with an opaque material 64 (FIG. 3, and column 4, lines 43-45). As constructed, the tip device 38 allows for the beam of light 36 to pass through the first end 66, the second end 68, and the tip portion 70 and the reflected beam 40 is allowed to pass through the tip portion 70, the second end 68, and the first end 66. The tip device 38 is extremely small and because of this size it can be inserted through gaps in most cells or through the membrane of a cell without damaging the cell. The tip 70 may be bathed in chemical coatings selected to react with biological compounds such as glucose (FIG. 3, and column 4, lines 52-63). As

shown in FIG. 4, the sample to be tested is a liquid 82 in a beaker 84. The tip portion 70 is inserted into the liquid 82 and at this point in time a beam of light, such as the beam of light 36, is transmitted into the liquid 82 (column 5, lines 23-27). The reflected beam of light 40 is reflected from the liquid 82 into the tip device 38 to the detector 42 (column 5, lines 42-44). The tip portion 156 of the sensor device 100 is inserted into a sample, such as the hand 162, to detect the presence of a concentration of material, such as for example glucose (column 6, lines 32-35).

Regarding claim 105, Applicant claims **an optical fiber comprising at least one fiber, a first and second end and a first diameter along an entire length of said optical fiber**. In contrast, Raskas, as shown in FIG. 3, the tip device 38 includes a non-tapered fiber optic portion 60 and a tapered fiber optic portion 62. Applicant further claims **a reagent pad comprising a flat membrane material impregnated with a dried reagent solution**. As is clearly seen in FIG. 3, the tip 70 is conical in shape. In Raskas the tip device 38 is extremely small and because of this size it can be inserted through gaps in most cells or through the membrane of a cell. The tip 70 may be bathed in chemical coatings. Raskas teaches that the tip portion is designed to penetrate a cell membrane. Clearly this tip portion does not anticipate **a reagent pad comprising a flat membrane material**. Furthermore, Applicant claims **said reagent pad further comprising a first flat surface for contacting the sample volume and a second flat surface, wherein said minimized area of said reagent pad minimizes a size of the sample volume required for testing**. Since the tip portion of Raskas is conical in shape, it does not have a flat surface for contacting the sample volume. As is clearly shown in FIG. 4 and described, the design of the tip portion does not minimize the size of the sample volume required for testing. The tip portion in Raskas requires a large sample volume. Additionally, Applicant claims **light impinges on said second flat surface and a reflected light, from said second flat surface, indicating changes in said optical properties is effectively returned through said optical fiber**. In contrast, Raskas teaches the tip portion is inserted into the liquid and a beam of light is transmitted through the tip portion into the liquid. The reflected beam of light is reflected from the liquid into the tip device. This is clearly not equivalent to Applicant's reagent pad that

reflects light. At least for all the reason given above, Applicant does not believe that Raskas anticipates Applicant's novel device. Applicant respectfully requests the Examiner withdraw the 35 U.S.C. 102(e) rejection of claim 105.

Regarding dependent claims 106-108 and 110, Applicant does not believe that Raskas anticipates the novel features of independent claim 105 from which these claims depend. As such, for at least all of the reasons given above for claim 105, Applicant respectfully requests the Examiner to withdraw the 35 U.S.C. 102(e) rejections of claims 106-108 and 110.

Regarding dependent claim 111, Applicant claims **the minimized size of the sample volume is measured by the photometrical detector in an in vitro blood glucose self-monitoring system**. In contrast, the glucose measuring of Raskas, which is shown in FIG. 6, is only for use as an in vivo system, not the in vitro use as Applicant claims. Applicant respectfully requests the Examiner to withdraw the 35 U.S.C. 102(e) rejection of claim 111.

Regarding independent claim 112, Applicant claims **a micro tube comprising a first open end, a second closed end and a first diameter along an entire length of said micro tube, said second closed end comprising an interior surface and an exterior surface wherein said first open end and said interior surface of said second closed end defines a cavity of said micro tube and said first open end and said exterior surface of said second closed end defines said entire length of said micro tube, said first open end receiving an optical probe from the photometrical detector where the optical probe passes through said cavity to said interior surface of said second end**. Applicant cannot find any equivalent structures in Raskas that would anticipate Applicant's claimed micro tube having a first diameter along an entire length and a defined cavity through which an optical probe passes. Applicant further claims **a reagent pad comprising a flat membrane material impregnated with a dried reagent solution**. As is clearly seen in FIG. 3, the tip 70 is conical in shape. In Raskas the tip device 38 is extremely small and because of this size it can be inserted through gaps in most cells or through the membrane of a cell. The tip 70 may be bathed in chemical

coatings. Raskas teaches that the tip portion is designed to penetrate a cell membrane. Clearly this tip portion does not anticipate **a reagent pad comprising a flat membrane material**. Furthermore, Applicant claims **said reagent pad further comprising a first flat surface for contacting the sample volume and a second flat surface, wherein said minimized area of said reagent pad minimizes a size of the sample volume required for testing**. Since the tip portion of Raskas is conical in shape, it does not have a flat surface for contacting the sample volume. As is clearly shown in FIG. 4 and described, the design of the tip portion does not minimize the size of the sample volume required for testing. The tip portion in Raskas requires a large sample volume. Additionally, Applicant claims **light impinges on said second flat surface and a reflected light, from said second flat surface, indicating changes in said optical properties is effectively returned through the optical probe**. In contrast, Raskas teaches the tip portion is inserted into the liquid and a beam of light is transmitted through the tip portion into the liquid. The reflected beam of light is reflected from the liquid into the tip device. This is clearly not equivalent to Applicant's reagent pad that reflects light. At least for all the reason given above, Applicant does not believe that Raskas anticipates Applicant's novel device. Applicant respectfully requests the Examiner withdraw the 35 U.S.C. 102(e) rejection of claim 112.

Regarding dependent claims 113, 114 and 116, Applicant does not believe that Raskas anticipates the novel features of independent claim 105 from which these claims depend. As such, for at least all of the reasons given above for claim 112, Applicant respectfully requests the Examiner to withdraw the 35 U.S.C. 102(e) rejections of claims 113, 114 and 116.

Regarding dependent claim 117, Applicant claims **the minimized size of the sample volume is measured by the photometrical detector in an in vitro blood glucose self-monitoring system**. In contrast, the glucose measuring of Raskas, which is shown in FIG. 6, is only for use as an in vivo system, not the in vitro use as Applicant claims. Applicant respectfully requests the Examiner to withdraw the 35 U.S.C. 102(e) rejection of claim 117.

REJECTION OF CLAIMS 105-117 UNDER 35 USC §103(a)

In the Office Action, the Examiner rejected claims 105-117 under 35 U.S.C. 103(a) as being unpatentable over Nomura (USP 5,859,937). The Examiner stated, "The Office has read the claimed "optical fiber" on the taught "optical fiber", the claimed "first end" on the taught "first end" and the claimed "second end" on the taught "textured site upon which reagent is deposited."" The Examiner further stated, "The Office has read Normura as teach the reagents are integral with the optical fiber as opposed to the claimed structure of being part of a pad which is attached to the fiber." The Examiner then stated, "It would have been desirable to modify Normura and place the reagents upon a pad and affix the pad to the end of the optical fiber as "obvious engineering design choice."" Applicant respectfully disagrees.

Nomura teaches a light-conducting fiber having a localized textured site thereon, wherein a reagent is deposited. Interaction of the reagent with an analyte specific to the reagent produces a response, such as development of a colored product, which is detectable by means of a change in characteristics of a light beam transmittable through the fiber. By means of the textured site and its increased surface area, the sensitivity of the device is greatly enhanced, such that less than 5 microliters of a fluid is needed for an analysis. The sensor is particularly useful in blood glucose determinations, requiring smaller blood samples than flat strip devices (Abstract). Nomura further teaches exclusion of red blood cells and/or other blood cellular components has been practiced utilizing reagent pads with filterative or membranous layers specifically formed or laminated thereon. This tends to increase the complexity of such devices, as well as increasing the volume of blood that must be applied (column 2, lines 3-9). Nomura teaches the primary advantage of the present invention, relating to its minimally invasive feature, is the presence of a large surface area in a very small, localized area, by which a greatly increased level of analyte-responsive reagent can be deposited and maintained (column 5, lines 16-20). This very large surface increase allows one to utilize a blood

droplet, for instance, that needs to wet only the tip of an optical fiber to a height of perhaps 2 mm, more preferably only 1 mm (column 5 lines 36-39).

Regarding claim 105, Applicant claims **a reagent pad comprising a flat membrane material impregnated with a dried reagent solution, said flat membrane material formed in a circular shape with a second diameter matching said first diameter for substantially covering said second end while minimizing an area of said reagent pad, said reagent pad further comprising a first flat surface for contacting the sample volume and a second flat surface, wherein said minimized area of said reagent pad minimizes a size of the sample volume required for testing**. Nomura teaches exclusion of red blood cells and/or other blood cellular components has been practiced in the art utilizing reagent pads with membranous layers specifically formed or laminated thereon. Nomura teaches that this tends to increase the complexity of such devices, as well as increasing the volume of blood that must be applied. As such, Nomura teaches that utilizing membranes is not desirable. One of ordinary skill in the art would not be motivated by the teachings of Nomura to use a membrane material as a reagent pad to minimize the sample volume required. Nomura further teaches that a large surface area for the reagent to be deposited on is needed to reduce the volume of the sample. One of ordinary skill in the art would not be motivated by this teaching to minimize the area of the reagent pad to minimize the sample volume. Applicant's novel use of a membrane material resulting in a minimized sample volume is unexpected in light of the teaching of Nomura. Nomura also teaches that the optical fiber needs to be wetted up the side by the sample. In contrast, Applicant's flat surface of the reagent pad contacts the sample. In light of the forgoing discussion, Applicant's reagent pad is not an "obvious engineering design choice." Nomura does not teach, suggest or motivate one of ordinary skill in the art to modify Nomura to produce Applicant's novel test tip device. Applicant respectfully requests the Examiner to withdraw this 35 U.S.C. 103(a) rejection of claim 105.

Regarding dependent claims 106-108, 110 and 111, Applicant does not believe that Nomura teaches, suggests or motivates one of ordinary skill in the art to modify

Nomura to produce Applicant's novel test tip device of independent claim 105 from which these claims depend. As such, for at least all of the reasons given above for claim 105, Applicant respectfully requests the Examiner to withdraw the 35 U.S.C. 103(a) rejections of claims 106-108, 110 and 111.

Regarding independent claim 112, Applicant claims **a micro tube comprising a first open end, a second closed end and a first diameter along an entire length of said micro tube, said second closed end comprising an interior surface and an exterior surface wherein said first open end and said interior surface of said second closed end defines a cavity of said micro tube and said first open end and said exterior surface of said second closed end defines said entire length of said micro tube, said first open end receiving an optical probe from the photometrical detector where the optical probe passes through said cavity to said interior surface of said second end**. Applicant cannot find any equivalent structures in Nomura that would teach, suggest or motivate one of ordinary skill in the art to modify Nomura to produce Applicant's novel test tip device having the claimed micro tube having a first diameter along an entire length and a defined cavity through which an optical probe passes. Applicant further claims **a reagent pad comprising a flat membrane material impregnated with a dried reagent solution that comprises optical properties that change with the quantity of the analyte, said flat membrane material formed in a circular shape with a second diameter matching said first diameter for substantially covering said second closed end while minimizing an area of said reagent pad, said reagent pad further comprising a first flat surface for contacting the sample volume and a second flat surface, wherein said minimized area of said reagent pad minimizes a size of the sample volume required for testing**. Nomura teaches exclusion of red blood cells and/or other blood cellular components has been practiced in the art utilizing reagent pads with membranous layers specifically formed or laminated thereon. Nomura teaches that this tends to increase the complexity of such devices, as well as increasing the volume of blood that must be applied. As such, Nomura teaches that utilizing membranes is not desirable. One of ordinary skill in the art would not be motivated by the teachings of Nomura to use a membrane material as a reagent pad to

minimize the sample volume required. Nomura further teaches that a large surface area for the reagent to be deposited on is needed to reduce the volume of the sample. One of ordinary skill in the art would not be motivated by this teaching to minimize the area of the reagent pad to minimize the sample volume. Applicant's novel use of a membrane material resulting in a minimized sample volume is unexpected in light of the teaching of Nomura. Nomura also teaches that the optical fiber needs to be wetted up the side by the sample. In contrast, Applicant's flat surface of the reagent pad contacts the sample. In light of the forgoing discussion, Applicant's reagent pad is not an "obvious engineering design choice." Nomura does not teach, suggest or motivate one of ordinary skill in the art to modify Nomura to produce Applicant's novel test tip device. Applicant respectfully requests the Examiner to withdraw this 35 U.S.C. 103(a) rejection of claim 112.

Regarding dependent claims 113, 114, 116 and 117, Applicant does not believe that Nomura teaches, suggests or motivates one of ordinary skill in the art to modify Nomura to produce Applicant's novel test tip device of independent claim 112 from which these claims depend. As such, for at least all of the reasons given above for claim 112, Applicant respectfully requests the Examiner to withdraw the 35 U.S.C. 103(a) rejections of claims 113, 114, 116 and 117.

Regarding dependent claims 109 and 115, the Examiner stated. "The court decided In re Boesch (205 USPQ 215) that optimization of a result variable is ordinarily within the skill of the art. A result effective variable is one that has well known and predictable results. The surface properties, such as hydrophilic or hydrophobic, are result effective variables with the well known and expected results of attracting or repelling aqueous materials. It would have been desirable when collecting a blood sample to make the collection hydrophilic to gain the advantages of permitting the sample to quickly spread and adhere to the surface. It would have been within the skill of the art to modify Raskas or Nomura and make the sample collecting surface hydrophilic to gain the above advantages and as optimization of a result effective variable." Applicant respectfully disagrees.

Applicant claims **said flat membrane material further comprises a uniformly porous hydrophilic membrane**. Applicant is claiming a characteristic of the membrane and is not claiming a result effective variable, such as "affinity to water". Furthermore, Nomura teaches that utilizing membranes is not desirable and increases the volume of blood that must be applied. The examiner is reminded that "the consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this characteristic should be used and would have reasonable likelihood of success, viewed in the light of the prior art." In re Dow Chemical Co. 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). On this record, the examiner has not provided a suggestion in the prior art, that **a uniformly porous hydrophilic membrane** be used to minimize a size of the sample volume required for testing. While a person of ordinary skill in the art may possess the requisite knowledge and ability to modify the sensor device taught by Nomura, the modification is not obvious unless the prior art suggested the desirability of the modification. In re Gordon, 733 F.2d 900, 902, 211 USPQ 1125, 1127 (Fed. Cir.1984). On this record, the examiner has failed to provide the evidence necessary to support a prima facie case of obviousness. Applicant respectfully requests the Examiner to withdraw the 35 U.S.C. 103(a) rejections of claims 109 and 115.

REJECTION OF CLAIMS 109 and 115 UNDER 35 USC §103(a)

In the Office Action, the Examiner rejected claims 109 and 115 under 35 U.S.C. 103(a) as being unpatentable over Raskas. The Examiner stated. "The court decided In re Boesch (205 USPQ 215) that optimization of a result variable is ordinarily within the skill of the art. A result effective variable is one that has well known and predictable results. The surface properties, such as hydrophilic or hydrophobic, are result effective variables with the well known and expected results of attracting or repelling aqueous materials. It would have been desirable when collecting a blood sample to make the collection hydrophilic to gain the advantages of permitting the sample to quickly spread and adhere to the surface. It would have been within the skill of the art to modify Raskas

or Nomura and make the sample collecting surface hydrophilic to gain the above advantages and as optimization of a result effective variable." Applicant respectfully disagrees.

Applicant claims **said flat membrane material further comprises a uniformly porous hydrophilic membrane**. Applicant is claiming a characteristic of the membrane and is not claiming a result effective variable, such as "affinity to water". Raskas teaches that a tip portion is designed to penetrate a cell membrane and requires a large sample volume. There is no teaching, suggestion or motivation to modify Raskas to provide **a uniformly porous hydrophilic membrane** as a tip portion. The examiner is reminded that "the consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this characteristic should be used and would have reasonable likelihood of success, viewed in the light of the prior art." In re Dow Chemical Co. 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). On this record, the examiner has not provided a suggestion in the prior art, that **a uniformly porous hydrophilic membrane** be used to minimize a size of the sample volume required for testing. The examiner has failed to provide the evidence necessary to support a prima facie case of obviousness. Applicant respectfully requests the Examiner to withdraw the 35 U.S.C. 103(a) rejections of claims 109 and 115.

REJECTION OF CLAIMS 112-117 UNDER 35 USC §103(a)

In the Office Action, the Examiner rejected claims 112-117 under 35 U.S.C. 103(a) as being unpatentable over Curry (US Pat. 4,974,929) in view of Pugh (US Pat. 5,736,103). The Examiner stated, "these claims are best understood as having a reagent pad attached to the end of a hollow tube or cone that is in communication with a means for optical analysis. The Office maintains the combination of Curry in view of Pugh teaches all of these elements and have been properly read on the instant claims." Applicant respectfully disagrees.

Curry teaches a biological fiber optic probe chemical indicator device comprising at least one strand of optical fiber terminating in a coupling arrangement with a

disposable sleeve assembly including a chemical indicator system for physiological substances. The disposable sleeve sensor element comprises a tubular housing with annular wall portions defining a female coupling channel means and a casing for a chemical reagent indicator (Abstract). The reagent matrix described by Curry is a cylindrically shaped element comprising a sheath 11 and end cap 12 defining a cavity filled with an optically active chemical indicator material 13 (column 3, lines 34-37). The reagent in Curry is contained in a cylinder. The tip of any optical fiber should be firmly against the chemical indicator material element 13 at interface junction 15 (column 3, lines 47-49). The sheath material 11 and the polymer matrix 17 of indicator element 13 may be comprised of any gas diffusable hydrophobic material such as silicon polymers, polyesters, or any gas permeable synthetic plastic material (column 4, lines 15-19). The device in Curry is intended to be immersed in bodily fluids. It is *critical* that, during use, the indicator sleeve tip be immersed in the body fluids, as in the fluid flow stream in a catheter (column 2, lines 62-64). The device in Curry depends on a large volume of flowing fluid as is presented by a catheter in a living body.

Pugh teaches a meter used in conjunction with a hollow, frustum-shaped disposable device to measure the concentration of an analyte in a sample of a biological fluid. The smaller end of the frustum has a porous membrane, to which a sample of the fluid may be applied. Preferably, a reagent in the membrane reacts with the analyte to cause a color change (Abstract). The membrane of Pugh, shown in the figures, is substantially larger than light source 38 and detector 40. It is further desirable to accommodate large samples, without dripping. Various designs can serve to retain excess sample. One is shown in FIGS. 12, 13, and 14 (column 6, lines 31-34).

Regarding claim 112, Applicant claims **a micro tube comprising a first open end, a second closed end and a first diameter along an entire length of said micro tube, said second closed end comprising an interior surface and an exterior surface wherein said first open end and said interior surface of said second closed end defines a cavity of said micro tube and said first open end and said exterior surface of said second closed end defines said entire length of said micro tube, said first open end receiving an optical probe from the photometrical detector where the**

optical probe passes through said cavity to said interior surface of said second end. In contrast to Applicant's micro tube, the indicator sleeve tip of Curry contains the encapsulated chemical indicator material. The optical fiber contacts the chemical material and cannot pass through to the end cap. The indicator sleeve tip is comprised of a gas permeable material that is hydrophobic. Curry teaches that it is *critical* that, during use, the indicator sleeve tip be immersed in the body fluids, as in the fluid flow stream in a catheter, in vivo. The hydrophobic characteristic of the sleeve tip prevents the chemical material from being washed into the body fluids. The gas permeability of the sleeve tip allows blood gasses to interact with the chemical material. Applicant additionally claims **the sample volume can be measured in vitro**. Curry clearly teaches the indicator sleeve tip must be used in vivo.

Applicant further claims **a reagent pad comprising a flat membrane material impregnated with a dried reagent solution that comprises optical properties that change with the quantity of the analyte, said flat membrane material formed in a circular shape with a second diameter matching said first diameter for substantially covering said second closed end while minimizing an area of said reagent pad, said reagent pad further comprising a first flat surface for contacting the sample volume and a second flat surface, wherein said minimized area of said reagent pad minimizes a size of the sample volume required for testing**. Pugh teaches a membrane that is substantially larger than a distant light source and detector. The Pugh membrane is attached over an opening in a cone. Pugh does not suggest that the membrane can be bonded to a closed end of a micro tube. Pugh further teaches it is further desirable to accommodate large samples, without dripping. Pugh does not teach **minimizing an area of said reagent pad wherein said minimized area of said reagent pad minimizes a size of the sample volume required for testing**. Pugh teaches away from minimizing the sample volume with the teaching of accommodating large samples.

In view of the forgoing discussion, one of ordinary skill in art would not be motivated to modify the sleeve tip of Curry, which must be used in vivo, with the large membrane of Pugh intended for in vitro testing. The addition of the membrane of Pugh would introduce chemical materials into the blood stream during the in vivo testing using

the Curry device. Furthermore, the chemical material would most likely be washed away in the blood stream rendering the device inoperable. Additionally, Curry and Pugh teach large sample volumes for testing which teaches away from Applicant's minimized sample volume. Furthermore, neither Curry nor Pugh discloses **means for bonding** a reagent pad to a closed end of a micro tube. Applicant believes that the examiner has provided the evidence necessary to support a prima facie case of obviousness. Applicant respectfully requests the Examiner to withdraw the 35 U.S.C. 103(a) rejection of claim 112.

Regarding dependent claims 113, 114, 116 and 117, Applicant does not believe that Curry in view of Pugh teaches, suggests or motivates one of ordinary skill in the art to modify Curry to produce Applicant's novel test tip device of independent claim 112 from which these claims depend. As such, for at least all of the reasons given above for claim 112, Applicant respectfully requests the Examiner to withdraw the 35 U.S.C. 103(a) rejections of claims 113, 114, 116 and 117.

Regarding dependent claim 115, the Examiner stated. "The court decided In re Boesch (205 USPQ 215) that optimization of a result variable is ordinarily within the skill of the art. A result effective variable is one that has well known and predictable results. The surface properties, such as hydrophilic or hydrophobic, are result effective variables with the well known and expected results of attracting or repelling aqueous materials. It would have been desirable when collecting a blood sample to make the collection hydrophilic to gain the advantages of permitting the sample to quickly spread and adhere to the surface. It would have been within the skill of the art to further modify Curry and make the sample collecting surface hydrophilic to gain the above advantages and as optimization of a result effective variable." Applicant respectfully disagrees.

Applicant claims **said flat membrane material further comprises a uniformly porous hydrophilic membrane**. Applicant is claiming a characteristic of the membrane and is not claiming a result effective variable, such as "affinity to water". Furthermore, Curry teaches that the sheath material is hydrophobic to prevent fluids from entering the indicator sleeve containing the chemical material. The examiner is reminded that "the consistent criterion for determination of obviousness is whether the prior art would have

suggested to one of ordinary skill in the art that this characteristic should be used and would have reasonable likelihood of success, viewed in the light of the prior art." In re Dow Chemical Co. 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). On this record, the examiner has not provided a suggestion in the prior art, that **a uniformly porous hydrophilic membrane** be used to minimize a size of the sample volume required for testing. While a person of ordinary skill in the art may possess the requisite knowledge and ability to modify the sensor device taught by Curry, the modification is not obvious unless the prior art suggested the desirability of the modification. In re Gordon, 733 F.2d 900, 902, 211 USPQ 1125, 1127 (Fed. Cir.1984). On this record, the examiner has failed to provide the evidence necessary to support a prima facie case of obviousness. Applicant respectfully requests the Examiner to withdraw the 35 U.S.C. 103(a) rejection of claim 115.

OTHER CITED REFERENCES

The Examiner also cited other references on PTO Form-892, but did not use these references to reject the claims. As implied by the fact that these references were not used to reject the claims, these additional references do not teach or suggest the features of Applicant's claimed invention. Thus, it is submitted that all claims are patentably distinct from these additional references.

C O N C L U S I O N

It is submitted that cited references, alone or in any combination, do not teach, suggest or motivate one of ordinary skill in the art to produce Applicant's novel test tip device. Therefore, it is submitted that claims 105-117 are patentably distinct from the cited references. Reconsideration of the application and a Notice of Allowance are earnestly solicited.

If there are any issues remaining which the Examiner believes could be resolved through either a Supplemental Response, an Examiner's Amendment, or otherwise if the

Examiner believes that further discussion would expedite the prosecution of this application, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number listed below.

Applicant believes that no extension fees are due in connection with this filing; however, Applicant hereby petition for an extension of time which may be required to maintain the pendency of this case, and for any required fee for such extension or any further fee required in connection with the filing of this Amendment, the Commissioner is hereby requested to notify Applicant of any payment due that is not otherwise paid with this letter.

Respectfully submitted,
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